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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,158	03/10/2004	Gary R. Braslawsky	037003-0308678	2640

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THOMAS CAWLEY
Pillsbury Winthrop, LLP
1600 Tysons Blvd.
McLean, VA 22102

EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/796,158

Applicant(s)

BRASLAWSKY ET AL.

Examiner

Marcela M. Cordero Garcia

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 26, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/04, 01/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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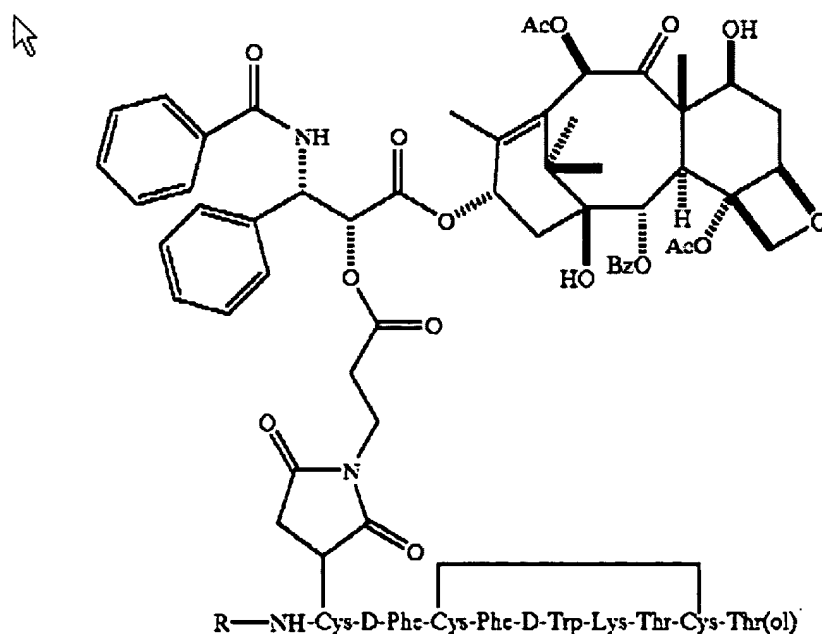
DETAILED ACTION

Claims 1-20 are pending in the application.

In response to the restriction requirement mailed on October 19, 2005, Applicants elect without traverse claims 15-20 (Group III), which are directed to methods of treating an SSTR-associated disorder. In response to the election of methods of treating an SSTR-associated disorder. In response to the election of species requirement, Applicants elect the somatostatin analog wherein A is SEQ ID NO: 1 (claim 16) and B is SEQ ID NO:4 (claim 17), which is equivalent to the CP1 somatostatin analog of SEQ ID NO: 5 (claim 18).

The species was searched and found free of the prior art. However, please note that no claims are drawn uniquely to this single species.

A second species was chosen by Examiner from amongst those instantly claimed. Examiner's species is



wherein A is cysteine or a peptide chain comprising one or more cysteine residues; R=H, wherein paclitaxel (a therapeutic agent) is bound to the cysteine

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residue via a thiol linkage and B= octreotide (D-Phe-Cys-Phe-DTrp-Lys-Thr-Cys-Thr(ol)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is rendered vague and indefinite because it is unclear whether the therapeutic agent to which A is bound via a thiol linkage includes the naturally occurring or synthetic somatostatin peptide, or fragment thereof (B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

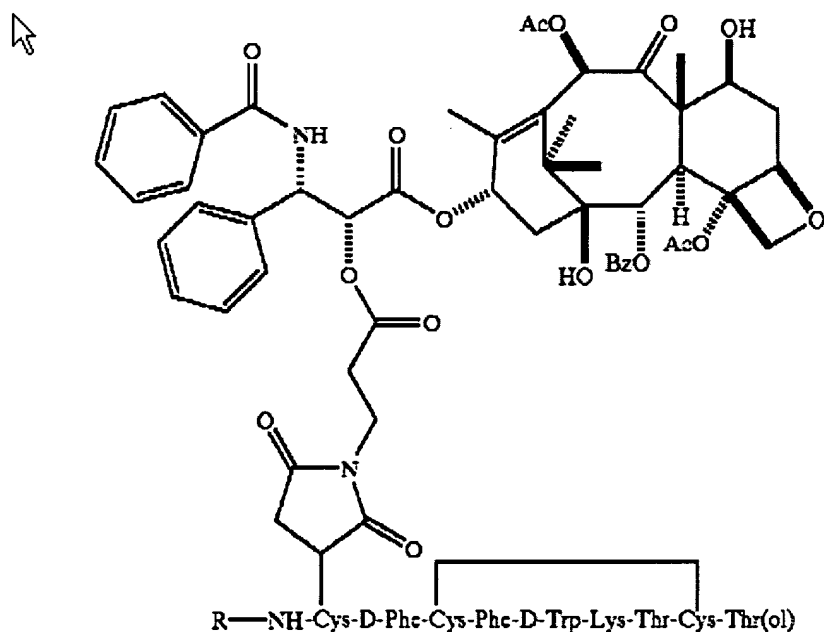
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6,552,007) or over Chen et al. (US 2002/0094964, cited in the IDS of January 11, 2005).

Chen et al. teaches a method of selectively killing cancer cells in a cell culture comprising contacting cells a somatostatin analog of the formula A-B:



wherein

A is cysteine, or a peptide chain comprising one or more cysteine residues, wherein paclitaxel (a cytotoxic therapeutic agent) is bound to the cysteine residue via a thiol linkage; and

B is a naturally occurring or synthetic somatostatin peptide, octreotide (D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Thr(ol)), which binds to a somatostatin

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receptor; and whereby a SSTR-associated disorder (cancer) is treated (See, e.g., column 5, lines 10-29; column 7, lines 4-63 in US '007 and [0060]-[0061] in Application '964).

Chen et al. do not teach direct administration of the compound above to a mammalian subject but do teach that the compound above may be used for treating a cancer patient by administering the anticancer compound to the cancer patient (See, e.g., column 7, lines 64-67 and column 8, lines 1-2 in US '007 and claim 11, [0070]-[0074] of Application '964).

Please note that that cancer is inherently an SSTR-associated disorder because somatostatin receptors (SSTRs) are overexpressed on the surfaces of cancer cells (e.g., column 1, lines 23-27 of US '007 and [0006] in Application '964).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of killing cancer cells of Chen et al. by administering it to cells in vivo (i.e., in a cancer patient) as taught by Chen et al. The skilled artisan would have been motivated to do so because Chen et al. teach that the anticancer compound taught above can be used for treating a cancer patient by administering such compound. There would have been a reasonable expectation of success, given that somatostatin analogs were known to preferentially target malignant tumor cells (e.g., column 1, lines 23-26, column 7, lines 4-63 in US '007 or [0006] and [0070]-[0074] in Application '964) and that taxol (paclitaxel) was known as an anticancer agent (e.g., column 5, line 5 and column 7, lines 59-60 in US '007 or [0068] in Application '964).

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Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowed.

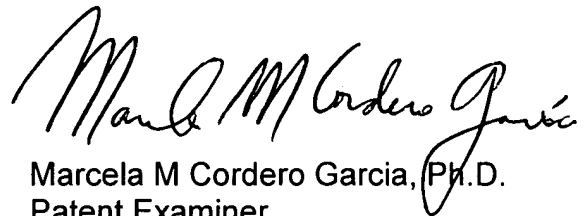
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 07/06



Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600